75 55920

28pgs (7)

No. 06-1498

FILED
NOV 28 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Daniel J. Popeo
Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave. N.W.
Washington, DC 20036
(202) 588-0302

Eric G. Lasker
Counsel of Record
James M. Sullivan
Spriggs & Hollingsworth
1350 I Street N.W.
Washington, DC 20005
(202) 898-5800

Dated: November 28, 2007

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

TABLE OF CONTENTS

Page

TABLE OF CITED AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 2

ARGUMENT 3

I. THE FEDERAL PRESENCE IN THE REGULATION AND APPROVAL OF PRESCRIPTION DRUGS IS FAR MORE SIGNIFICANT THAN THE FEDERAL PRESENCE THAT LED THIS COURT TO REJECT THE PRESUMPTION AGAINST PREEMPTION IN *BUCKMAN* 3

II. THERE IS NO PRESUMPTION AGAINST PREEMPTION WHERE A STATE LAW CLAIM INTRUDES UPON A FEDERAL AGENCY'S PRIMARY JURISDICTION 10

III. THERE IS NO PRESUMPTION AGAINST IMPLIED CONFLICT PREEMPTION 14

CONCLUSION 21

TABLE OF CITED AUTHORITIES

Page(s)

Cases:

Bates v. Dow AgroSciences LLC,
544 U.S. 431 (2005) 1, 16, 17
Brown v. Hotel and Restaurant Employees and Bartenders INT'L Union Local 54,
468 U.S. 491 (1984) 10, 11, 15, 20
Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001) ..... *passim*
California v. ARC America Corp.,
490 U.S. 93 (1989) 15
Chicago & Northwest Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981) 20
CIBA Corp. v. Weinberger,
412 U.S. 640 (1973) 14
Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) 15, 16
Conference of State Bank Supervisors v. Conover,
710 F.2d 878 (D.C. Cir. 1983) 17
Crosby v. Nat'l Foreign Relations Trade Council,
530 U.S. 363 (2000) 15
DeCanas v. Bica,
424 U.S. 351 (1976) 15
Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist., 541 U.S. 246 (2004) 3
Far Eastern Conference v. United States,
342 U.S. 570 (1952) 11
Fidelity Fed. Sav. and Loan Ass'n v. de la Cuesta,
458 U.S. 141 (1982) 15, 16
Florida Lime & Avocado Growers, Inc. v. Paul,
373 U.S. 132 (1963) 16

Page(s)

Free v. Bland,
369 U.S. 663 (1962) 15
Gade v. Nat'l Solid Wastes Mgmt. Ass'n,
505 U.S. 88 (1992) 15
Geier v. Am. Honda Motor Co.,
529 U.S. 861 (2000) 1, 8, 16, 17, 20
Gibbons v. Ogden,
22 U.S. 1 (1824) 14
Heckler v. Chaney,
470 U.S. 821 (1985) 12
Hines v. Davidowitz,
312 U.S. 52 (1941) 16
Int'l Paper Co. v. Ouellette,
479 U.S. 481 (1987) 20
Irving v. Mazda Motor Co.,
136 F.3d 764 (11th Cir.),
cert. denied, 525 U.S. 1018 (1998) 16
Kanter v. Warner Lambert Co.,
99 Cal. App. 4th 780 (2002) 3
Medtronic v. Lohr,
518 U.S. 470 (1996) 5, 8, 17
Merck KGAA v. Integra Lifesciences I, Ltd.,
545 U.S. 193 (2005) 13
Penn. Employees Benefit Trust Fund v. Zeneca Inc., 499 F.3d 239 (3d Cir. 2007) 8
Rice v. Santa Fe Elevator Corp.,
331 U.S. 218 (1947) 15
Rutherford v. United States,
806 F.2d 1455 (10th Cir. 1986) 14
Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.,
902 F.2d 222 (3d Cir. 1990) 13
Schering Corp. v. Heckler,
779 F.2d 683 (D.C. Cir. 1985) 12

Page(s)

Sprietsma v. Mercury Marine,
537 U.S. 51 (2002) 16, 17
Tutoki v. Celebrezze,
375 F.2d 105 (7th Cir. 1967) 14
United States v. Locke,
529 U.S. 89 (2000) 1, 4
Weinberger v. Bentex Pharms., Inc.,
412 U.S. 645 (1973) 13

Constitutional Provisions:

U.S. Const., Art. VI, cl. 2 ..... 17, 20

Statutes:

Food and Drug Administration Modernization Act
of 1997, S. Rep. 105-43, 1997 WL 394244 6

Food, Drug, and Cosmetic Act (FDCA),
21 U.S.C. § 301, *et seq.* ..... *passim*
21 U.S.C. § 355 6
21 U.S.C. § 356b 7

MICH. COMP. LAWS § 600.2946(5) 12, 13

MICH. COMP. LAWS § 600.2946(5)(a) 4

Page(s)

Regulations:

21 C.F.R. § 200.5 7

21 C.F.R. § 201.57 7

21 C.F.R. § 202.1(e)(5) 7

21 C.F.R. § 202.1(e)(6) & (7) 7

21 C.F.R. § 314.50 6

21 C.F.R. § 314.80 6

21 C.F.R. § 314.81 7

21 C.F.R. § 314.81(b)(3) 7

21 C.F.R § 314.81(d) 7

21 C.F.R. Part 201 7

21 C.F.R. Part 202 7

21 C.F.R. Part 203 7

Other Authorities:

71 Fed. Reg. 3922 (Jan. 24, 2006) 9

Federalist No. 78 ..... 18, 20

Page(s)

J.A. DiMasi, *et al.*, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Economics 151-85 (2003) 6

The Records of the Federal Convention of 1787, (M. Farrand ed., rev. ed. 1937) 18, 19

Trends in FDA Drug Enforcement 2006: An Expert Analysis of the Latest Warning Letters, (FDAnews Management Report 2006) 8

INTEREST OF *AMICUS CURIAE*

The Washington Legal Foundation ("WLF") is a non-profit, public-interest law and policy center based in Washington, D.C., with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free enterprise principles, individual rights, a limited and accountable government, and the proper use of our state and federal judicial systems. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke*, 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as the Federal Food, Drug, and Cosmetic Act (FDCA) at issue here.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing due solely to its interest in the important preemption issues raised by this case.

---

[1] WLF hereby affirms that no counsel for either party authored any part of this brief, and that no person or entity other than *amicus curiae* and its counsel provided financial support for the preparation and submission of this brief. By blanket letters of consent, all parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court unanimously held that plaintiffs' claims that a medical device manufacturer secured FDA approval for a § 510(k) medical device through fraud on the FDA were impliedly preempted because such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgments and objectives." *Id.* at 350. In so ruling, this Court rejected plaintiffs' assertion that it should apply a presumption against preemption to such claims, explaining that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'" and noting that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347.

Just six years after its clear ruling in *Buckman*, this Court is again faced with the issue of whether fraud-on-the-FDA claims are preempted. In its ruling below, the Second Circuit rejected the core holding of *Buckman* and held that fraud-on-the-FDA claims asserted by plaintiffs to meet the exception to Michigan's product liability statute are *not* preempted. The Second Circuit reached this contrary result based in large part on its holding that it should apply the very same presumption against preemption this Court rejected. *See* Pet. App. 18a-19a.

WLF files this *amicus* brief because the Second Circuit's confusion over the proper scope of a presumption against preemption highlights the need for further guidance on the

issue by this Court.[2] While the claims here should be held preempted even if a presumption applied, the arguments contrary to a presumption against preemption here are in fact far stronger than they were in *Buckman*, because the degree of federal involvement in the approval of prescription drugs dwarfs that at issue in the approval of § 510(k) medical devices. More fundamentally, however, a presumption against preemption is completely inapplicable here because plaintiffs' fraud-on-the-FDA claims (1) intrude upon regulatory determinations within the primary jurisdiction of FDA and (2) conflict directly with federal law. WLF respectfully requests that the Court clarify that no anti-preemption presumption can be applied in such circumstances.

ARGUMENT

I. THE FEDERAL PRESENCE IN THE REGULATION AND APPROVAL OF PRESCRIPTION DRUGS IS FAR MORE SIGNIFICANT THAN THE FEDERAL PRESENCE THAT LED THIS COURT TO REJECT THE PRESUMPTION AGAINST PREEMPTION IN *BUCKMAN*

In applying a presumption against preemption, the Second Circuit failed to recognize the longstanding, extensive role that the federal government plays in the approval of the safety and efficacy of prescription drugs. "[A]n 'assumption' of nonpre-emption is not triggered when the State regulates in

---

[2] As the Court has recently noted, the proper application of a "presumption against preemption" is an issue "on which not all Members of this Court agree." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004).

an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108 (2000).

In rejecting any presumption against preemption in *Buckman*, this Court focused on the federal interest in maintaining control over the FDA regulatory process by which medical device applicants secure approval for Section 510(k) medical devices. As the Court explained, "the § 510(k) process sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device." *Buckman*, 531 U.S. at 348. Accordingly, the Court concluded that policing fraud against the FDA in the Section 510(k) process "is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347.[3]

For prescription drug manufacturers pursuing a new drug application (NDA), far more even than for manufacturers of Section 510(k) devices, the manufacturers' "dealings with the FDA [a]re prompted by the [FDCA], and the very subject of [the applicants'] statements [are] dictated by that statute's provisions." *Id.* at 347-48. This Court recognized in *Buckman* that the Section 510(k) process "lacks the . . . rigor" of FDA's premarket approval (PMA) review of Class III medical devices, *id.* at 348, a process modeled after and substantially

---

[3] Like the fraud-on-the-FDA claims at issue in *Buckman*, under the Michigan statutes, plaintiffs seeking to bring claims against a prescription drug manufacturer must establish that the manufacturer "[i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the [FDCA]" and "the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a), reprinted at Pet. App. 42a.

identical to FDA's NDA process for prescription drugs.[4] As the Court previously had noted in *Medtronic, Inc. v. Lohr*:

> The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. . . . As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits negative response from the FDA, and gets processed very quickly.

518 U.S. 470, 478-79 (1996) (citations omitted).

Nevertheless, the *Buckman* Court rejected a presumption against preemption because "to achieve its limited purpose, the § 510(k) process imposes upon applicants a variety of requirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies under this exception." 531 U.S. at 348-49.

The requirements imposed by FDA on manufacturers of prescription drugs and the corresponding scope of the federal presence mandating the inapplicability of a presumption against preemption here are far more detailed and substantial. Like PMA-approved Class III medical devices, prescription drugs are subject to perhaps the most extensive federal regulatory scheme governing any consumer product. As the

---

[4] *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 794 (2002) ("The substantial similarity between the premarket approval process [for medical devices] and new drug application processes compels the conclusion that the latter also establishes a federal requirement with respect to labeling that can have preemptive effect.").

United States Congress recognized a decade ago, the NDA process is rigorous; new drug applications "typically run to hundreds of thousands of pages," and the process of securing NDA approval for a prescription drug "takes an average of 15 years and costs in the range of $500 million." Food and Drug Administration Modernization Act of 1997, S. Rep. 105-43, *available at* 1997 WL 394244, at *6. These costs have only increased since. *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Economics 151-85 (2003) (calculating that total R&D costs per new drug brought to market in the United States have now reached $802 million).

A drug manufacturer seeking approval to market a prescription drug is subject to specific FDA regulatory determinations at every stage of the pre-approval development, approval, labeling, marketing, and post-marketing approval process. To obtain FDA approval of a prescription drug, a pharmaceutical company must submit voluminous scientific evidence to the agency in accordance with the statutory requirements set forth in Section 355 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*.

Pursuant to a broad grant of regulatory authority under the Act, FDA has enacted detailed regulatory reporting requirements for New Drug Applications addressing, *inter alia*, the format and organization of the application, pharmacologic and toxicologic studies, clinical investigation data, case reports forms, patent information, and marketing-exclusivity issues. *See* 21 C.F.R. § 314.50. Once a drug has received FDA approval, FDA continues to subject drug manufacturers to extensive regulatory requirements mandating frequent submissions of adverse drug experience reports, *see* 21 C.F.R. § 314.80, and regular submissions of new studies and other information relevant to the continued approval of the

drug, *see* 21 C.F.R. § 314.81. FDA may also require Phase IV post-marketing studies to gather additional information regarding the drug's safety, efficacy, or optimal use. *See* 21 U.S.C. § 356b. FDA retains continuing regulatory control over the content and format of drug labels. *See* 21 C.F.R. § 201.57; *see also* 21 C.F.R. Part 201. FDA's postmarketing authority has been enhanced further through the recent enactment of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, §§ 901-21, 121 Stat. 823 (2007).

FDA also imposes strict regulatory requirements on drug manufacturers in their direct communications with physicians. *See* 21 C.F.R. § 200.5 ("mailing of important information about drugs"); § 201.57 and Part 201 (labeling); Part 202 ("Prescription Drug Advertising"); Part 203 ("Prescription Drug Marketing"). In seeking to market a drug to physicians, pharmaceutical companies also are required to "submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product." 21 C.F.R. § 314.81(b)(3). If the company fails to submit such information to the FDA, the agency "may withdraw approval of the application and, thus, prohibit continued marketing of the drug product." *Id.* § 314.81(d).

FDA comprehensively regulates the content and format of prescription drug advertising, including requiring that the advertisement "present a 'true statement' of information in brief summary relating to side effects, contraindications, and effectiveness," *id.* § 202.1(e)(5), and prohibiting advertisements that – as defined in detail in the regulations – are or may be "false, lacking in fair balance, or otherwise misleading," *id.* § 202.1(e)(6) & (7). The FDA vigorously

monitors drug company communications with the medical community and takes regulatory action where it deems such action is appropriate.[5] *See also Penn. Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239 (3d Cir. 2007) (holding consumer fraud claims against prescription drug manufacturers impliedly preempted); *id.* at 250 (Supreme Court opinions in "*Medtronic* and *Geier* add to the preemption analysis by suggesting that state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority").

The federal presence here is also stronger than that in *Buckman* because the federal government's role in the approval of prescription drugs substantially predates its role in the regulation of medical devices. In discussing the competing state and federal interests in the safety of Section 510(k) medical devices in *Lohr*, this Court noted that "[d]espite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasing role in the protection of the health of our people." *Lohr*, 518 U.S. at 475. The Court explained, however, that the FDA had not been authorized to regulate the approval of medical devices until the enactment of the Medical Device Amendments of 1976, some twenty years before. *Id.* at 475-76. In sharp contrast, FDA began regulating the approval of prescription drugs with the enactment of the Food and Drug Act of 1906. The federal government has thus played a central role in ensuring the safety of prescription drugs for over one hundred years.

---

[5] For example, in 2005, FDA issued 102 drug warning letters to drug manufacturers in connection with promotional activity. *See* Trends in FDA Drug Enforcement 2006: An Expert Analysis of the Latest Warning Letters (FDAnews Management Report 2006).

The federal interest in maintaining control over the relationship between FDA and prescription drug manufacturers in the NDA process is substantial and would be significantly impeded if courts could misuse a presumption against preemption to allow fraud-on-the-FDA claims under the Michigan statute. The substantial nature of the federal interest in the disclosures to FDA as part of the regulation of prescription drugs was clearly explained in January 2006, when the FDA promulgated a Final Rule on labeling for prescription drugs. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

In the preamble to this Final Rule, FDA warned that in recent years, state law "product liability lawsuits have directly threatened the [FDA's] ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the [FDCA]." *Id.* at 3934. FDA explained that "[s]tate law actions can rely on and propagate interpretations of the [FDCA] and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate." *Id.* FDA thus stressed that "[i]f State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation would be disrupted." *Id.* at 3969.

It cannot be disputed that "there has been a history of significant federal presence" in the regulation and approval of prescription drugs, a federal presence far more significant than that which led this Court to reject a presumption against

preemption in *Buckman*. Whereas the *Buckman* Court confronted the adverse consequences of fraud-on-the-FDA claims only in the context of a limited Section 510(k) review, in this case, the Court is faced with claims that would interfere with scores if not hundreds of different FDA submission requirements that are routinely imposed on drug manufacturers during each stage of the multi-year NDA process and during FDA's subsequent oversight of approved drugs. The Second Circuit's reliance on a presumption against preemption below was in error, and this Court should so hold.

II. THERE IS NO PRESUMPTION AGAINST PREEMPTION WHERE A STATE LAW CLAIM INTRUDES UPON A FEDERAL AGENCY'S PRIMARY JURISDICTION

The Second Circuit's reliance on a presumption against preemption is also in error because it fails to account for the fact that the questions that must be resolved under the Michigan statute fraud on the FDA exception would require a court to intrude upon the primary jurisdiction of FDA. A presumption against preemption is not appropriate where it would undercut the discretion and expertise entrusted by Congress to the federal agencies, which this Court has consistently protected. *See, e.g.*, *Buckman*, 531 U.S. at 347-53 (no presumption against preemption given FDA's primary responsibility to police fraud against the Agency); *Brown v. Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 502 (1984) (NLRB's primary jurisdiction protected by special "presumption [in favor] of federal preemption [that] applies even when the state law regulates

conduct only arguably protected by federal law.");[6] *Far East Conference v. United States*, 342 U.S. 570, 574-75 (1952) (action should be dismissed to afford agency with primary jurisdiction opportunity to review in first instance).

The Court explained the need to not lightly intrude on a federal agency's primary jurisdiction over fifty years ago:

> [I]n cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially defined. Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.

Far East Conference, 342 U.S. at 574-75.

Each of the two showings necessary to invoke the fraud on the FDA exception in the Michigan products liability statute requires a factfinder under state law to intrude upon FDA's primary jurisdiction:

---

[6] While *Brown* addressed a special preemption doctrine applicable to matters within the primary jurisdiction of NLRB, the principles behind the Court's rejection there of any presumption against preemption are equally applicable here.

First, the factfinder is required to determine that the drug manufacturer has intentionally withheld from or misrepresented information to the FDA concerning its drug that is required to be submitted under the FDCA. *See* MICH. COMP. LAWS § 600.2946(5), reprinted at Pet. App. 42a. But as this Court recognized in *Buckman*, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives" that "can be skewed by allowing fraud-on-the-FDA claims under state tort law." 531 U.S. at 348; *see also id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration."). Thus, for example, this Court has held that courts may not review FDA determinations whether to take enforcement action with regard to prescription drugs. *See Heckler v. Chaney*, 470 U.S. 821 (1985). The Court explained that "an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise" and that "[t]he agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831-32; *see also Schering Corp. v. Heckler*, 779 F.2d 683, 685-86 (D.C. Cir. 1985) (decision by FDA whether to exercise its enforcement authority "involve a complex balancing of an agency's priorities, informed by judgments 'peculiarly within its expertise,' and they are therefore ill-suited for judicial review") (internal citation omitted).

The unavoidable intrusion upon FDA's primary jurisdiction required for purposes of determining whether FDA has been defrauded is particularly significant because of the complexity of FDA regulations regarding the information that should be provided to FDA by drug companies and FDA's

discretion in many instances in determining whether or not certain types of information should be submitted. Thus, "it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005); *cf. Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("agency decisions are frequently of a discretionary nature or frequently require expertise," resulting in "administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations").

Second, under Michigan's fraud on the FDA exception, the factfinder must determine that the drug would not have been approved or would have had its approval withdrawn if the information had been accurately submitted. *See* MICH. COMP. LAWS § 600.2946(5), reprinted at Pet. App. 42a. This Court has recognized FDA's primary jurisdiction over the NDA approval of prescription drugs. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 654 (1973). "The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations. Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the administrative agency, while the court stays its hand." *Id.*

Under the Michigan statute, plaintiffs must establish that "the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." MICH. COMP. LAWS § 600.2946(5), reprinted at Pet. App. 42a. Thus, "an essential element of proof . . . would be a showing that if the FDA had passed upon [a prescription drug] according to statutory and constitutional

standards, it would have been approved or exempted." *Tutoki v. Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967). As the United States Court of Appeals for the Seventh Circuit has explained, "[t]his determination is a matter within the primary jurisdiction of the FDA. *Id.* "The possible conflict of a judicial determination of this question with a[n] . . . FDA determination on [the drug] strengthens our view that the doctrine of primary jurisdiction should be applied." *Id.*; *cf. Rutherford v. United States*, 806 F.2d 1455, 1461 (10th Cir. 1986) ("[T]he intent behind the [FDCA] was to give the agency the primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise. *See also CIBA Corp. v. Weinberger*, 412 U.S. 640, 643-44 (1973).").

By failing to recognize FDA's primary jurisdiction over both steps in the Michigan statute's fraud on the FDA exception, the Second Circuit erroneously hinged its opinion on a presumption against preemption. No such presumption applies here.

III. THERE IS NO PRESUMPTION AGAINST IMPLIED CONFLICT PREEMPTION

Thirdly, the Second Circuit erred in relying on a presumption against preemption because such presumption, if ever appropriate, is not appropriate in cases giving rise to implied conflict preemption. Rather, the sole question for the courts in determining whether implied conflict preemption applies is the existence of a conflict between federal and state law.

The Court repeatedly has made clear that "'[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of

our Constitution provided that the federal law must prevail.'" *Fidelity Fed. Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (principle that "state law is nullified to the extent that it actually conflicts with federal law" is "not inapplicable here simply because real property law is a matter of special concern to the States"); *Brown*, 468 U.S. at 502-03 (same with respect to local interest in crime control). Indeed, even where the State has a "compelling interest" in preservation of its law, "under the Supremacy Clause, for which our preemption doctrine is derived, any state law, . . . clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (internal quotations and citations omitted); *DeCanas v. Bica*, 424 U.S. 351, 357 (1976) ("[E]ven state regulation designed to protect vital state interests must give way to paramount federal legislation."); *Free v. Bland*, 369 U.S. 663, 666 (1962)(same) (citing *Gibbons v. Ogden*, 22 U.S. 1 (1824)).[7]

---

[7] Counsel has found no case in which the Court has relied on a presumption against preemption in the face of an actual conflict between state and federal law. In *California v. ARC Am. Corp.*, 490 U.S. 93, 101-06 (1989), the Court suggested a presumption against preemption, but any such presumption played no ascertainable part in the Court's holding. *See id.* (mentioning presumption as something to "overcome," but finding no federal-state conflict for the presumption to overcome); *see also Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000) (deferring on question whether presumption against preemption applies in context of implied conflict preemption). This Court has, by contrast, applied a presumption against preemption in cases involving express preemption, *e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517-18 (1992), or field preemption, *e.g.*, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). However, even in cases involving statutory construction, the "presumption against preemption" has not been consistently applied and is not free from controversy. It has been ignored in many recent express preemption

(continued...)

Such a federal-state conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). *E.g.*, *de la Cuesta*, 458 U.S. at 153. "[B]oth forms of conflicting state law are 'nullified' by the Supremacy Clause, and [this Court] has assumed that Congress would not want either kind of conflict." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (internal citations omitted). Thus, once a federal-state conflict is established, preemption is "inescapable and requires no inquiry into congressional design." *Fla. Lime*, 373 U.S. at 142-43; *see also Geier*, 529 U.S. at 869 ("ordinary pre-emption principles . . . instruct us to read statutes as pre-empting state laws (including common-law rules) that 'actually conflict' with the statute or federal standards promulgated thereunder").

As both the D.C. Circuit and Eleventh Circuit have recognized, this Court's teaching cannot coexist with a presumption against preemption in implied conflict preemption cases. *See Irving v. Mazda Motor Co.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no

---

[7](...continued)
cases, *e.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (relying on "natural[] read[ing]" of express preemption clause without any mention of presumption), and squarely rejected as a guide to interpreting express preemption clauses by at least two Members of this Court, *e.g.*, *Cipollone*, 505 U.S. at 544 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part) ("Under the Supremacy Clause, . . . our job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly but in accordance with their apparent meaning."); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 457 (2005) (opinion of Thomas, J.) (same).

presumption exists against preemption."), *cert. denied*, 525 U.S. 1018 (1998); *Conference of State Bank Supervisors v. Conover*, 710 F.2d 878, 882 (D.C. Cir. 1983) ("the 'presumption [against preemption]' inquiry is not relevant here, for the only question before us is whether admittedly conflicting regulations are valid").[8]

Indeed, the Framers left no doubt that there can be no presumption against preemption of conflicting state law, and that federal law is supreme without need for a showing of a Congressional preemptive intent, by placing that statement of intent within the text of the Supremacy Clause. *See* U.S. Const., art. VI, cl. 2 ("[T]he laws of the United States . . . shall be the supreme Law of the Land . . . *any Thing in the*

---

[8] A close review of this Court's recent preemption jurisprudence in cases involving state tort law claims demonstrates that it is the existence or non-existence of a conflict – rather than any presumption – that has informed the Court's rulings. *See Bates*, 544 U.S. 431 (2005) (no express preemption of state tort law claims alleging inefficacy of pesticide because EPA does not evaluate pesticide efficacy nor approve pesticide labeling in that regard, but holding that fraud and failure-to-warn claims might be preempted to the extent based on requirements inconsistent with EPA regulation); *Sprietsma*, 537 U.S. 51 (2002) (no implied preemption where federal coast guard had not taken position on whether propeller guards should be required on motor boats); *Buckman*, 531 U.S. 341 (2001) (fraud-on-the-FDA claims impliedly preempted in light of conflict with FDA regulatory authority); *Geier*, 529 U.S. 861 (2000) (state tort law claims for failure to install airbags impliedly preempted due to conflict with federal law despite savings clause in National Traffic and Motor Vehicle Act precluding finding of express preemption); *Lohr*, 518 U.S. 470 (1996) (rejecting express preemption of state tort law claims involving Section 510(k) medical device because the generality of FDA requirements in approving such devices did not provide basis for state-federal law conflict); *see also id.* at 504 (Breyer, J., in controlling concurrence, explaining that preemption would be necessary if conflict existed).

Constitution or Laws of any State to the Contrary notwithstanding.") (emphasis added). During the Constitutional Convention, the delegates specifically debated whether the source of federal law supremacy should be an affirmative assertion by Congress – *i.e.* some statement as might be needed to rebut a presumption against preemption – or the fundamental hierarchy between federal and state laws. They decided on the latter and charged the courts to declare conflicting state laws void without awaiting any statement of preemptive intent by Congress. *See id.*; *see also* The Federalist No. 78 (Alexander Hamilton) ("The interpretation of the laws is the proper and peculiar province of the courts. . . . [I]n regard to the interfering acts of a superior and subordinate authority, ... it will be the duty of the judicial tribunals to adhere to [the supreme law].").

The Framers' rejection of any presumption against conflict preemption is made evident by the history behind the drafting of the Supremacy Clause. Early in the Convention, Governor Edmund Randolph proposed fifteen resolutions, primarily drafted by James Madison, which became known as the Virginia Plan. The sixth resolution dealt generally with the affirmative powers of Congress – the functional equivalent under the Virginia Plan of the Constitution's Article I, Section 8. I The Records of the Federal Convention of 1787, at 21 (M. Farrand ed., rev. ed. 1937). Among the powers allocated to Congress under this resolution was the authority "to negative all laws passed by the several States, contravening in the opinion of the National Legislature the articles of Union." *See id.* In other words, under this proposal, Congress would be required to declare whether conflicting state law would be preempted.

In response to the Virginia Plan, William Patterson, proposed nine alternative resolutions which became known as

the New Jersey Plan or the Small State Plan. The sixth of Patterson's resolutions was in substance and concept, if not in form, similar to the current language of the Supremacy Clause. *See id.* at 245. Patterson's sixth resolution differed from Randolph's power to negative state laws in that the former was not proposed as one of Congress's affirmative powers. All such powers under the Small State Plan were proposed in Patterson's second resolution. *See id.* at 243. The supremacy concept was instead offered as a separate resolution, distinct from legislative powers and listed after the fifth resolution establishing the federal judiciary. *See id.* at 244. That is, the courts – not Congress – would determine whether there was a preemptive conflict between federal and state law.

Resolution of the competing proposals came when the Convention debated the report of the Committee of the whole House. As he had done throughout the debates, *see id.* at 169 (June 8, 1787), 317 (June 19, 1787), James Madison warned against the "propensity of the States to pursue their particular interests in opposition to the general interest" and advocated "the negative on the laws of the States as essential to the efficacy & security of the Genl. Govt," 2 The Records of the Federal Constitutional Convention of 1787, at 27 (M. Farrand ed., rev. ed. 1937). Roger Sherman responded, "Such a power involves a wrong principle, to wit, that a law of a State contrary to the articles of the Union, would if not negatived, be valid & operative." *Id.* Randolph's proposal for a legislative power to negative state laws was thereafter defeated by a vote of three to seven. *See id.*

The Convention then immediately adopted by unanimous consent an alternative proposal by Luther Martin which is in substance similar to Patterson's sixth resolution and in form almost identical to the current Supremacy Clause. *See id.* at 28-29. Consistent with the structure of Patterson's plan, the

adopted text that became the Supremacy Clause does not mention any affirmative authority of Congress to repeal state law, but rather made federal law supreme over conflicting state law in all instances. *See* U.S. Const., art. VI, cl. 2; *see also* The Federalist No. 78.

Conflict preemption cases thus represent the paradigmatic operation of the Supremacy Clause to resolve conflicts between state and federal law. In declining to find preemption "[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims," Pet. App. 24a, the Second Circuit below contravened the fundamental constitutional principles underlying implied conflict preemption and departed from this Court's unambiguous teaching. *See Geier*, 529 U.S. at 884-85 ("[C]onflict pre-emption . . . turns on the identification of 'actual conflict,' and not on an express statement of preemptive intent. . . . [T]he Court has never before required a specific, formal agency [or congressional] statement identifying conflict in order to conclude that such a conflict in fact exists."); *Int'l Paper Co. v. Ouellette*, 479 U.S. 481 (1987) ("[I]t is not necessary for a federal statute to provide explicitly that particular state laws are pre-empted."); *Brown*, 468 U.S. at 501 ("[e]ven in the absence of such express language or implied congressional intent to occupy the field, we may nevertheless find state law to be displaced to the extent that it actually conflicts with federal law"); *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) ("[W]hen Congress has chosen to legislate pursuant to its constitutional powers, then a court must find local law pre-empted by federal regulation whenever the 'challenged state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."'") (citations omitted).

The Second Circuit's application of a presumption against preemption to avoid implied conflict preemption of Respondent's fraud-on-the-FDA claims was in error. No such presumption exists against implied conflict preemption.

CONCLUSION

The Second Circuit's rejection of this Court's holding in *Buckman* based on a misplaced "presumption against preemption" highlights the need for further guidance from this Court on the proper scope, if any, of such a presumption. For the reasons set forth herein, WLF respectfully requests that this Court make clear that no such presumption can be applied in cases involving drug manufacturer regulatory submissions in the approval and regulation of prescription drugs due to the long-standing significant federal presence in that area. WLF also requests that this Court confirm that no presumption against preemption exists in cases intruding upon a federal agency's primary jurisdiction or in cases of implied conflict preemption.

Respectfully submitted,

Daniel J. Popeo
Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave. NW
Washington, D.C. 20036
(202) 588-0302

Eric G. Lasker
Counsel of Record
James M. Sullivan
Spriggs & Hollingsworth
1350 I Street NW
Washington, D.C. 20005
(202) 898-5800

November 28, 2007